K060897 Page 1 of 2

MEDIGROUP, Inc.

JUL 18 2006

510(k) Summary

Basic Information

Submitter:	Medigroup, Inc. 14 A Stonehill Road Oswego, IL 60543
Establishment Registration Number:	#1450420
Contact:	John A. Navis, President
Telephone:	(630) 554-5533
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E-mail	inavis@medigroupinc.com
Date of Submission	March 30, 2006

Device Information

Trade Name:	Embedding ™ Tool.
Common Name:	Catheter Tunneling Device.
Classification Name:	78 FJS, accessory.
Class:	II

Predicate Devices

510(k) 823331 Tunnelor® Tool, issued January 26, 1983.

Product Description

The Embedding™ Tool consists of a gently curved handle portion made of rigid PVC with a detachable titanium tip and a separate titanium cap.

Intended Use

The Embedding ™ Tool is used to "embed" about 30cm of the external portion of a peritoneal dialysis catheter into the subcutaneous tissue immediately following the initial tunneling step of catheter implantation in order to be retrieved at a later time to begin peritoneal dialysis. After this secondary tunneling step, the titanium tip is unscrewed from the tool handle and functions as a plug at the catheter end. The titanium cap is then screwed onto the open end of the titanium tip to close it off.

This Embedding™ Tool is intended to be used by the same physician at the same time and setting when he is implanting the catheter initially. As such, it can be used with any patient who is a suitable candidate for delayed peritoneal dialysis catheter utilization.

Substantial Equivalence

The "handle" or tunneling part of this Embedding™ Tool is made of the same rigid polyvinyl compound (RPVC) and has a similar configuration as the Tunnelor® Tool, predicate device 510(k) 823331. The configuration of the tip of the new device is similar to the shape of the tip in the predicate device, but made of titanium instead of RPVC.

510(k) Summary

Testing

Functional testing has been performed to demonstrate mechanical integrity. Clinical evaluation at a dialysis center showed the Embedding™ Tool functioned as intended.

Conclusions

The Embedding™ Tool works as designed and intended. Its use is intended for use by physicians familiar with proper catheter tunneling techniques.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2006

Mr. John A. Navis
President
Medigroup, Inc.
14 A Stonehill Road
OSWEGO IL 60543-9400

Re: K060897
Trade/Device Name: TE-1000 Embedding™ Tool
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: June 26, 2006
Received: June 27, 2006

Dear Mr. Navis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060897

Device Name: TE-1000 Embedding™ Tool

Indications For Use:

This device can be used to embed most known brands and styles of PD catheters when the nephrologist determines this action is in the best interest of the patient, however, only immediately after successful catheter implantation.

The Embedding™ Tool is indicated for embedding the external portion of most PD catheters subcutaneously in anticipation of future retrieval of that part of the catheter, provided that:

- The embedding procedure is done immediately following PD catheter implantation.
- Catheter patency has been completely established.
- The normally external part of the PD catheter can be embedded.
- The patient is a candidate for delayed onset of PD treatment.
- The patient is a candidate for PD.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060897